K111547

APR 12 2012

510(k) Summary
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29-Nov-11

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Official Contact: Tsuyoshi Sugino – Regulatory Affairs Manager

Proprietary or Trade Name: BILI-THERAPY Pad Type

Common/Usual Name: Neonatal phototherapy unit.

Classification Name/Code: LBI – Neonatal phototherapy unit.
21CFR 880.5700
Class II

Device: BILI-THERAPY Pad

Predicate Device: Respironics – Bili-Tx K070180

Device Description:
The BILI-THERAPY Pad Type is a Bili-therapy unit available with large and small pads.

The light source can be mounted to the incubator / warmer or an optional stand.

The unit provides light therapy for the treatment of hyperbilirubinemia, commonly known as neonatal jaundice, during the newborn period in the hospital / institutional settings. The BILI-THERAPY Pad Type emits a narrow band of blue light considered to be the most effective in the treatment of hyperbilirubinemia. Light is generated in the light source and conducted to the patient via light guides to the pads. The pads are reusable and are intended to be covered with disposable pad covers. Eye masks are recommended for use with this product but are not included in this submission. Reference to commercially available eye masks is provided in the instructions for use.

Indications for Use:
The BILI-THERAPY Pad Type is a phototherapy unit intended for the treatment of neonatal hyperbilirubinemia.

Environment of Use: Hospital or institutional

Summary of substantial equivalence

The Atom Phototherapy Unit
The BILI-THERAPY Pad Type was compared to the predicate Respironics BiliTx (K070180).

Indications for Use – The BILI-THERAPY Pad Type is a phototherapy unit intended for the treatment of neonatal hyperbilirubinemia.

The BILI-THERAPY Pad Type has the same intended use (treatment of hyperbilirubinemia) as the Respironics BiliTx (K070180).

Patient Population – The BILI-THERAPY Pad Type is indicated for Neonates as is the predicate.

Environment for use – The BILI-THERAPY Pad Type functions in hospital / institutional settings as does the predicate (hospital/institutional or home setting)

Prescriptive – The BILI-THERAPY Pad Type is prescriptive as is the predicate.

Design and Technology – The BILI-THERAPY Pad Type has equivalent design and features as the predicate and has the identical technology to the predicate.

Performance and Specifications – The BILI-THERAPY Pad Type has equivalent specifications of performance as the predicate.

Compliance with standards – The BILI-THERAPY Pad Type and predicate device declare compliance with IEC 60601-1, IEC 60601-1-2, and IEC 60601-2-50.

Device Comparison

	BILI-THERAPY Pad Type	Respironics Bili-Tx (K070180)
General Attributes		
Indications for Use	The BILI-THERAPY Pad Type is a phototherapy unit intended for the treatment of neonatal hyperbilirubinemia.	The Bili-Tx is intended to treat hyperbilirubinemia through phototherapy
Patient Population	Neonatal	Neonatal
Environment of Use	Hospital or institutional	Home or hospital/institutional
Prescriptive	Yes	Yes
Patient Connection	Yes via pad	Yes with Bili-Tx Fiber optic light panel
Technology	Blue light-emitting diodes (LEDs)	Blue light-emitting diodes (LEDs)
Technical specifications		
Dimensions	Light Source: 150w x 220d x 160h mm Large Pad 170w x 480d mm Small Pad 120w x 330 mm Stand 550 x 500-1000mm H (adjustable) Rack 105w x 270d x 69 mm	Illuminator 16.10 cm x 7.40 cm (6.34 in x 2.92 in) Neonatal fiber-optic panel: 127 mm x 177.8 mm
Weight	Light Source approx. 2.1 kg Large Pad 0.8 kg Small Pad: 0.6 kg Stand: 10 kg Rack 0.8 kg	1.3 Kg (2.86 lb)
Irradiation Intensity	High: 53 $\mu W/cm^2/nm$ +/-25% Medium: 40 $\mu W/cm^2/nm$ +/-25% Low: 26.5 $\mu W/cm^2/nm$ +/-25% (measurement obtained by BiliBlanket® meter placed on the pad surface without a pad cover) Change in irradiance over 6 hours +/- 10% (in effective area) Effective irradiated area: Large Pad: 15 x 30 cm Small Pad 10 x 15 cm	Neonatal fiber-optic panel: 90 $\mu W/cm^2/nm$ Measured with the Joey™ Dosimeter (JD-100) Neonatal fiber-optic panel: 127 mm x 17.78 mm
Wavelength	Peak 450 to 480 nm	Peak between 450 nm and 485 nm
Sound level	60 dB or less	52 dB
Power Supply	Rated, Voltage 100-240 VAC Power consumption 68 VA, frequency 50/60 Hz Working voltage range 100-240 VAC +/- 10%	(Input) 100 – 240 VAC, 50/60 Hz, 1.0 A
Operating Temperature	Ambient Temperature: 10-30°C Relative Humidity 30-85% (non-condensing)	15°C to 35°C
Storage Temperature	Ambient Temperature :0-50°C Relative Humidity 30-75% (non-condensing)	-20 °C to 55 °C
Mounting Options	Light Source can be mounted to BILI-HOLDER on the warmer or to optional stand	Not specified

Conclusion

The BILI-THERAPY Pad Type is substantially equivalent to the predicate Respironics BiliTx (K070180) in indications for use, patient population, and environment for use, technology characteristics, specifications / performance and compliance with international standards

Performance Testing

We have performed bench tests which included the list below and found that the BILI-THERAPY Pad Type met all pass /fail criteria, cited standards requirements and was found to be equivalent in comparison to the predicate.

- IEC 60601-1: Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment 2, 1995

- IEC 60601-1-2: Collateral standard: Electromagnetic Compatibility - Requirements and Tests (Edition 2:2001 with Amendment 1:2004; Edition 2.1 (Edition 2:2001 consolidated with Amendment 1:2004)).

- IEC 60601-2-50: 2009 Medical Electrical Equipment - Part 2-50: Particular requirements for the basic safety and essential performance of infant phototherapy equipment.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Atom Medical Corporation
C/O Mr. Paul E. Dryden
President
Regulatory Consultant for Atom Medical
ProMedic, Inc.
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APR 12 2012

Re: K111547
Trade/Device Name: BILI-THERAPY Pad Type
Regulation Number: 21 CFR 880.5700
Regulation Name: Neonatal Phototherapy Unit
Regulatory Class: II
Product Code: LBI
Dated: April 9, 2012
Received: April 10, 2012

Dear Mr. Dryden:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: _____ (To be assigned)

Device Name: BILI-THERAPY Pad Type

Indications for Use:

The BILI-THERAPY Pad Type is a phototherapy unit intended for the treatment of neonatal hyperbilirubinemia.

Prescription Use X (Part 21 CFR 801 Subpart D) **or** **Over-the-counter use __** (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Wei Chen for RZC 4/11/12

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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